



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,517	06/12/2001	Vincent J. Sullivan	64,149-097	4080

26253 7590 06/04/2004

DAVID W. HIGHNET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
----------	--------------

3761

//

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,517

Applicant(s)

SULLIVAN ET AL.

Examiner

Darwin P. Erez

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 52-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,9,12-24,27-33,35-51 and 66-69 is/are rejected.
- 7) ☒ Claim(s) 3,7,10,11,25,26,34,70 and 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 52-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected in, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 14-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 14 recites the limitation "said cylindrical passage" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4-6, 8, 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,941,867 to Kao in view of US 6,070,575 to Gonda.

8. As to claims 1, 6, 8, 12, 13, Kao teaches a cartridge comprising a cylindrical body **106** having opposed ends, a passage through said body through said opposed ends, a powdered medicament **107** stored in the passage and burstable plastic membranes **104, 112** sealing the passage at said opposite ends.

Kao is silent with regards to the membranes composed of polyolefin and wherein the membrane has a burst pressure of less than 10 ATM.

Gonda teaches a medicament cartridge having a burstable membrane, wherein the membrane has a burst pressure of less than 40 bar or 40 ATM (col. 12, lines 51-56).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the burstable membrane of Kao to have a burst pressure of less than 40 ATM (which covers the range of less than 10 ATM) since it is desirable to have a low burst pressure membrane for easier actuation of said cartridge. Furthermore, it would have been obvious to use a polyolefin membrane since polyolefin is a widely known plastic material.

Art Unit: 3761

9. As to claim 4 and 5, Kao fails to specifically teach the first and second membranes having different angles of orientation. However, the orientation of the first and second membranes is a mere design choice and that one of ordinary skill in the art could orient the first membrane at a different angle from the second membrane.

10. As to claim 9, the above combination discloses the claimed invention except for the polyethylene having a thickness of 0.3-1.5 mils and a burst pressure of less than 5 ATM. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at said limitation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3761

12. Claims 1, 2, 4, 5, 8, 12, 13, 23-24, 35-40, 42, 43 and 66-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 16, 17, 20 and 26-32 of U.S. Patent No. 6,644,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations recited in the claims of the instant application are also taught in the claims of the patent, i.e. both claim medicament device having a housing comprising an inlet port, an outlet port, and a chamber including a cartridge comprising a body having opposed ends, a passage formed through said body, said opposed ends having burstable polyolefin membranes, the cartridge having a burst pressure of less than 10 ATM, a powdered medicament stored in the passage; wherein the membranes are oriented at different angles or about right angles; wherein a syringe connected to the inlet port. The method claims recited in the instant application is also recited in claims 29-32 of the patent.

13. Claims 1,9, 27-33, 41, 44-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14 and 21 of U.S. Patent No. 6,644,309 ('309) in view of claim 21 of U.S. Patent No. 6,443,152 ('152).

The '309 patent teaches all the limitations of the claims as recited in the rejection above except for the membrane having a thickness of 0.3 to 1.5 mils; wherein the housing is formed of two opposed thermoformed polymeric sheets; wherein a pressure

Art Unit: 3761

actuator is formed between the sheets. However, it would have been obvious to add said limitation since the commonly owned '152 patent recites said limitations.

14. Claims 14-18 and 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 16, 17, 20, 26-28 of U.S. Patent No. 6,644,309 ('309) in view of claim 21 of US 6,070,575 to Gonda.

The '309 patent claims a cartridge comprising a body having opposed ends, a passage extending through the body, a medicament stored in the passage, said opposed ends having burstable polymeric films stretched taut over and bonded to the surfaces of the opposed ends of the body; wherein the burstable polymeric films are oriented at different angles or about right angles relative to one another; wherein the medicament is powder, wherein the burstable polymeric films have a burst pressure of less than 5 atm. The '309 patent is silent with regards to the end having the burstable polymeric film as being convex.

Gonda teaches a medicament cartridge having a burstable membrane, wherein the end of the cartridge having the burstable membrane is convex. (col. 6, line 27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the end of the '309 patent to include a convex end since having a convex end is a mere design choice that is known in the art, as taught by Gonda,

Art Unit: 3761

15. Claims 14 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 16, 17, 20, 26-28 of U.S. Patent No. 6,644,309 ('309) in view of claim 21 of US 6,070,575 to Gonda and in further view of claim 21 of U.S. Patent No. 6,443,152 ('152).

The above combination of the '309 patent/Gonda teaches all the limitations of the claim as recited in the rejection above except for the membrane having a thickness of 0.3 to 1.5 mils. However, it would have been obvious to add said limitation since the commonly owned '152 patent recites said limitation in claim 21.

Allowable Subject Matter

16. Claims 3, 7, 10, 11, 25, 26, 34, 70 and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703)308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

de

GK
GLENN K. DAWSON
PRIMARY EXAMINER